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Proposed Re-evaluation Decision PRVD2017-17

Zinc Oxide and Its Associated End-use Products

(Swimming Pool and Spa Uses)

Consultation Document

(publié aussi en français)

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Overview

What is the Proposed Re-evaluation Decision?

After a re-evaluation of zinc oxide, the Health Canada Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of pest control products containing zinc oxide for sale and use in Canada.

The focus of this re-evaluation is the use of zinc oxide in swimming pools and spas. The use of zinc oxide as a wood preservative was previously re-evaluated (RVD2011-06) and is not considered in this re-evaluation.

An evaluation of available scientific information found that products containing zinc oxide do not present unacceptable risks to human health or the environment when used according to the label directions. This evaluation and the proposed decision affects all end-use products for use in pools and spas containing zinc oxide registered in Canada.

This Proposed Re-evaluation Decision is a consultation document[1] that summarizes the science evaluation for zinc oxide and presents the reasons for the proposed re-evaluation decision. The information is presented in two parts. The Overview describes the regulatory process and key points of the evaluation, while the Science Evaluation provides additional technical information on the assessment of zinc oxide.

The PMRA will accept written comments on this proposal up to 90 days from the date of publication of this document. Please forward all comments to Publications (see contact information on the cover page of this document).

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment.

What is Zinc Oxide?

Zinc oxide is registered for use in domestic class swimming pool and spa products. Zinc oxide is co-formulated with trichloro-s-triazinetrione, which releases free chlorine when in contact with water. Products are formulated as tablets, which are immersed into water in pool skimmer baskets, chlorine feeders, and/or automated chlorinators.

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1 *"Consultation statement" as required by subsection 28(2) of the Pest Control Products Act.*

Health Considerations

Can Approved Uses of Zinc Oxide Affect Human Health?

Zinc oxide is unlikely to affect your health when used according to the label directions.

Potential exposure to zinc oxide may occur when applying the puck to pool/spa water, when entering treated water, or by accidentally swallowing pool/spa water. When assessing health risks, two key factors are considered: the levels at which no health effects occur and the levels to which people may be exposed. The levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). As such, sex and gender are taken into account in the risk assessment. Continued registration is only supported for uses that are determined as having no health risks of concern.

Toxicology studies in laboratory animals describe potential health effects resulting from various levels of exposure to a chemical and identify dose levels at which no effects are observed. Zinc oxide and other zinc salts generally do not exhibit toxicological effects following natural exposure routes and realistic dosing. Adverse effects following exposure are not expected.

Risks in Residential and Other Non-Occupational Environments

Estimated risk for residential and other non-occupational exposure is not of concern.

Exposure from residential use of zinc oxide is not of concern under the registered conditions of use (pools and spas).

Occupational Risks from Handling Products Containing Zinc Oxide

Exposure from use of zinc oxide pool and spa products by professional pool and spa workers is not of concern under the registered conditions of use.

Residues in Water and Food

Dietary risks from food and water are not of concern.

Zinc oxide is not registered for use on food or outside of swimming pools and spas; therefore, dietary exposure to zinc oxide through the consumption of food and drinking water is not of concern.

Environmental Considerations

What Happens When Zinc Oxide is Introduced into the Environment?

When zinc oxide is used according to the current label directions, exposure to the environment is negligible, and the risk to the environment is expected to be of no concern.

Value Considerations

Zinc oxide possesses antimicrobial properties, and no issues of antimicrobial resistance have been reported from its use following several years of registration for pools and spas.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human health and the environment. These directions must be followed by law. As a result of the re-evaluation of zinc (present as zinc oxide), no additional risk mitigation measures are proposed by the PMRA. To meet the current labelling standards, the following label updates are proposed:

- Storage label statements
- Disposal label statements
- Environmental label statements

What Additional Scientific Information is Required?

No additional data are required.

Next Steps

Before making a final re-evaluation decision on zinc oxide, the PMRA will consider any comments received from the public in response to this consultation document. A science-based approach will be applied in making a final decision on zinc oxide. The PMRA will then publish a Re-evaluation Decision[2] that will include the decision, the reasons for it, a summary of comments received on the proposed decision and the PMRA response to these comments.

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[2] *"Decision statement" as required by subsection 28(5) of the Pest Control Products Act.*

Science Evaluation

1.0 Introduction

Zinc oxide is registered for use in swimming pools and spas. It is also a component of Ammoniacal Copper Zinc Arsenate-type wood preservatives; however, these products were previously re-evaluated (RVD2011-06). The focus of this re-evaluation is the use of zinc oxide in swimming pools and spas only.

Following the re-evaluation announcement for zinc oxide, the registrant of the technical grade active ingredient in Canada indicated that they intended to provide continued support for all uses included on the label of end-use products in Canada.

Currently registered products containing zinc oxide for swimming pool and spa use are listed in Appendix I.

2.0 Use Description of Zinc Oxide

Zinc oxide is registered for use in domestic class swimming pool and spa products. Products are formulated as chlorine-zinc oxide pucks that are immersed into water in pool skimmer baskets, chlorine feeders, and/or automated chlorinators. The chlorine, present as trichloro-s-triazinetrione, is a source of stabilized chlorine and a well-established pool and spa sanitizer.

All end use products contain 89.6% trichloro-s-triazinetrione and 0.4% zinc oxide. The registered application rate for the chlorine zinc oxide pucks is to maintain free available chlorine content of 1-3 parts per million in swimming pool water. When used as directed, the concentration of zinc ion generated by the pucks in swimming pool water is expected to be between 150–200 parts per billion.

3.0 The Technical Grade Active Ingredient

Identity of the Technical Grade Active Ingredient

Common Name		Zinc Oxide
Chemical Family		Metal Oxide
Chemical Name		
1	**International Union of Pure and Applied Chemistry (IUPAC)**	Zinc oxide
2	**Chemical Abstracts Service (CAS)**	Zinc oxide
CAS Registry Number		1314-13-2

Molecular Formula	ZnO
Structural Formula	ZnO
Molecular Weight	81.39 g/mol

4.0 Human Health

Zinc is an essential dietary element in the body and is an integral component of various metabolic processes. It naturally occurs in the environment and is thus present in food and drinking water. Zinc oxide has a long history of use, and it is a common component in both pharmaceuticals and cosmetics.

Exposure to zinc oxide may occur through handling the product in a residential setting, by entering treated water, and /or through accidental ingestion of treated pool and spa water.

4.1 Toxicological Summary

Zinc oxide and other zinc salts generally do not exhibit toxicological effects following natural exposure routes and realistic dosing. Zinc oxide is of low acute toxicity via the oral, dermal, and inhalation routes. It is mildly irritating to skin and eyes, and has low potential for dermal sensitization. In short- and long-term studies, exposure to zinc oxide generally does not result in adverse effects except for at very high doses. No concerns for developmental or reproductive toxicity were identified in the available information. Zinc oxide is not expected to be carcinogenic. Zinc oxide is classified as Generally Recognized As Safe (GRAS) by the United States Food and Drug Administration.

Given the low toxicity of zine oxide, no toxicological endpoints have been established for quantitative risk assessment by the PMRA. As a result, the PMRA has used a qualitative approach to assess the potential risks (pool and spa uses) of zinc oxide to human health.

4.2 Occupational and Residential Exposure and Risk

Professional workers, homeowners, and bystanders can be exposed to zinc oxide through handling the product and/or by entering treated swimming pools/spas. Dermal exposure is considered to be the primary route of exposure; however, accidental oral exposure may also occur.

Current end-use product labels recommend the use of rubber gloves when handling the products and placing the tablets into the pool system. When used as directed, the concentration of zinc ions generated by the pucks in swimming pool or spa water is expected to be less than 200 parts per billion. This concentration is well below the Canadian drinking water aesthetic objective guideline of 5000 parts per billion for zinc (water with zinc levels above 5000 parts per billion tend to be cloudy and develop a greasy film when boiled). There is no health-based maximum acceptable concentration established for zinc. With the existing label directions, low toxicity, and the low concentration in pool/spa water, exposure from handling the products or contact with treated water is not expected to be of concern.

Overall, zinc oxide use in pools and spas is not expected to pose any significant increase in exposure to zinc relative to dietary sources. No additional mitigation measures are proposed.

4.3 Dietary Exposure and Risk

Zinc is a mineral distributed in all plants and animals. Zinc is ubiquitous in the environment and a natural constituent of the human diet. Zinc oxide is not registered for use on any food commodity and is not expected to contaminate drinking water sources when label directions are followed. On this basis, dietary exposure to zinc oxide (from use in residential pools and spas) through the consumption of food and drinking water is not expected.

No additional risk mitigation measures are proposed.

4.4 Aggregate Exposure

Aggregate exposure is the total exposure to a single pesticide that may occur from food, drinking water, residential, and other non-occupational sources as well as from all known or plausible exposure routes (oral, dermal and inhalation). Based on the registered use pattern for zinc oxide, aggregate exposure is not expected.

4.5 Cumulative Exposure and Risk

The *Pest Control Products Act* requires that the PMRA consider the cumulative exposure to pesticides with a common mechanism of toxicity. While zinc oxide may share a common moiety with other zinc-based active ingredients, the potential risks from cumulative exposure to zinc are not of concern given the low toxicity profile and the limited exposure potential.

5.0 Environment

Zinc is naturally present in the environment. Based on the current use pattern in pools and spas, exposure to non-target organisms in the environment is expected to be low, and the potential environmental risks are not expected to be of concern.

No additional risk mitigation measures are proposed. Updates to standard labels statements are proposed to meet the current labelling standard (Appendix II).

6.0 Value

Zinc oxide possesses antimicrobial properties, and no issues of antimicrobial resistance have been reported from its use following several years of registration for pools and spas.

7.0 Pest Control Product Policy Considerations

7.1 Toxic Substances Management Policy Considerations

The Toxic Substances Management Policy (TSMP) is a federal government policy developed to provide direction on the management of substances of concern that are released into the environment. The TSMP calls for the virtual elimination of Track 1 substances [those that meet all four criteria outlined in the policy, i.e. persistent (in air, soil, water and/or sediment), bio-accumulative, primarily a result of human activity and toxic as defined by the *Canadian Environmental Protection Act*].

During the review process, zinc oxide was assessed in accordance with the PMRA Regulatory Directive DIR99-03 and evaluated against the Track 1 criteria. The PMRA has reached the following conclusions:

Metals are naturally occurring elements and are not candidates for Track 1. The use of zinc oxide in pools and spas is not expected to result in the entry of TSMP Track 1 substances into the environment.

7.2 Contaminants and Formulants of Health or Environmental Concern

During the re-evaluation of zinc oxide, contaminants in the technical grade active ingredient were compared against the *List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern* maintained in the *Canada Gazette*.[3] The list is used as described in the PMRA Notice of Intent NOI2005-01 and is based on existing policies and regulations including: DIR99-03 and DIR2006-02, and taking into consideration the Ozone-depleting Substance Regulations, 1998, of the *Canadian Environmental Protection Act* (substances designated under the Montreal Protocol). The PMRA has reached the following conclusion:

Based on the manufacturing process used, impurities of human health or environmental concern, including TSMP Track 1 substances identified in the *Canada Gazette*, are not expected to be present in the product.

8.0 Incident Reports

Starting April 2007, registrants have been required by law to report incidents, including adverse effects to health and the environment, to PMRA within a set time frame. As of 27 June 2017, no incident reports involving zinc oxide have been submitted to the PMRA.

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[3] *Canada Gazette, Part II, Volume 139, Number 24, pages 2641–2643: List of Pest Control Product Formulants and Contaminants of Health or Environmental Concern and in the order amending this list in the Canada Gazette, Part II, Volume 142, Number 13, pages 1611-1613. Part 1 Formulants of Health or Environmental Concern, Part 2 Formulants of Health or Environmental Concern that are Allergens Known to Cause Anaphylactic-Type Reactions and Part 3 Contaminants of Health or Environmental Concern.*

9.0 Organisation for Economic Co-operation and Development Status of Zinc Oxide

Canada is part of the Organisation for Economic Co-operation and Development (OECD), which provides a forum in which governments can work together to share experience and seek solutions to common problems. As part of the re-evaluation of an active ingredient, PMRA takes into consideration recent developments and new information on the status of an active ingredient in other jurisdictions, including OECD member countries.

Zinc oxide is currently acceptable for use in other OECD countries, including the United States, Australia, and New Zealand. As of 16 August 2017, no decision by an OECD member country to prohibit all uses of zinc oxide for health or environmental reasons has been identified.

10.0 Proposed Re-evaluation Decision

The PMRA, under the authority of the *Pest Control Products Act* and Regulations, is proposing continued registration of pest control products containing zinc oxide for sale and use in Canada. Label updates to meet current labelling standard are proposed (Appendix II).

List of Abbreviations

OECD	Organisation for Economic Co-operation and Development
PMRA	Pest Management Regulatory Agency
TSMP	Toxic Substances Management Policy

Appendix I Registered Zinc Oxide Products as of 5 June 2017

Registration Number	Marketing Class	Registrant	Product Name	Formulation Type	Guarantee
24425	Technical	American Chemet Corporation	Zinox 350 Technical	Dust	76% Zinc Oxide
32764	Technical	Sani-Marc Inc..	Sani Marc Zinc Oxide	Solid	79.5% Zinc Oxide
30786	Domestic	Alliance Trading Inc.	Eazee Pucks	Tablets	0.4% Zinc Oxide 89.6% Trichloro-s-triazinetrione
28201		Groupe D'Achat M.P. Inc.	Tablettes Supreme		
32640			Pisci-Z		
32215		Independent Pool Group Inc.	IPG Aqua Foot		
25115		Sani-Marc Inc.	Super "Z" Pucks		
26680			Aqua Foot		
31747			Sani-Marc Spa Zinc		
32163			Tri Zinc Tab		
26411		Sani-Marc Inc. D.B.A. Purity	Pure Power Z Puck Stabilized Chlorinating Tablets		
28200		Sani-Marc Inc. D.B.A Kool Kit	Kool Tab		
31585		Trevi	Tech-Zen		

Appendix II Label Amendments for Products Containing Zinc Oxide

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Information on labels of currently registered products should not be removed unless it contradicts the label statements provided below.

A submission to request label revisions will be required within 90 days of finalization of the re-evaluation decision.

I) The following statements must be included in a section entitled **STORAGE**:

"To prevent contamination store this product away from food or feed."

II) The following statements must be included in a section entitled **DISPOSAL**:

"DO NOT reuse the empty containers. Dispose in household garbage. Unused or partially used products should be disposed at provincially or municipally designated hazardous waste disposal sites."

III) The following statements must be included in a section entitled **DIRECTIONS FOR USE**:

"DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes."

References

A. LIST OF STUDIES/INFORMATION SUBMITTED BY REGISTRANT(S)

Unpublished information

PMRA Document Number	Reference
2386054	2014, N/A, DACO: 2.14.1 CBI Colour
2386055	2014, N/A, DACO: 2.14.2 CBI Physical State
2386056	2014, N/A, DACO: 2.14.3 CBI Odour
2386058	2014, N/A, DACO: 2.14.4 CBI Melting Point / Melting Range
2386059	2014, N/A, DACO: 2.14.7 CBI Water Solubility (mg/L)
2450526	2014, NA, DACO: 2.14.12 CBI UV/Visible Absorption Spectra
2450527	2014, NA, DACO: 2.14.13 CBI Stability (Sunlight, Temperature, Metals)
2450530	2014, NA, DACO: 2.14.6 CBI Density or Specific Gravity
1537301	1995, Technical Chemistry File, Zinc Oxide., DACO: 2.1,2.10,2.11,2.12, 2.13,2.14,2.2,2.3,2.4,2.5,2.6,2.7,2.8,2.9
2386047	2014, N/A, DACO: 2.11.2 CBI Description of Starting Materials
2386046	2014, N/A, DACO: 2.11.1 CBI Manufacturing Summary
2386048	2014, N/A, DACO: 2.11.3 CBI Detailed Production Process Description
1537293	Chemistry Technical File, ZNO [CBI Removed], Memos on Zinc Oxide., DACO: Memo
2386052	2014, N/A, DACO: 2.13.2 CBI Confirmation of Identity
2386053	2014, N/A, DACO: 2.13.3 CBI Batch Data
2499351	2015, na, DACO: 2.13.3 CBI Batch Data
2499350	2015, na, DACO: 2.13.3 CBI Batch Data
481650	Part 2 Chemistry; ZNO [CBI Removed], LSS # 95109)

Published information

PMRA Document Number	Reference
1160496	UNITED STATES ENVIRONMENTAL PROTECTION AGENCY R.E.D. FACTS-ZINC SALTS.(H-7508W;EPA-738-F-92-007) AUGUST 1992.DACO: 11.1

B. ADDITIONAL INFORMATION CONSIDERED

Published Information

PMRA Document Number	Reference
2765534	PRVD2010-03 Proposed Re-evaluation Decision Heavy Duty Wood Preservatives: Creosote, Pentachlorophenol, Chromated Copper Arsenate (CCA) and Ammoniacal Copper Zinc Arsenate (ACZA)
	Parmeggiani, L. (Editor). Encyclopaedia of Occupational Health and Safety. (Third Revised Edition), Volume 2. International Labour Office Geneva.
	Canadian Center for Occupational Health and Safety. CHEMINFO database (May 1996)
	Cumpston AG.; Zinc Alloys and Compounds. Encyclopaedia of Occupational Health and Safety, Vol 2, pages 2340-2342, 1983
	Mulay, I., Roy, R., Knox, B., Suhr, N., Delaney, W., Trace-metal analysis of cancerous and non-cancerous human tissues. Journal of the National Cancer Institute, Volume 47, 1971
	Lin, H., Chan, W., Fong, Y., Newberne, P., Zinc Levels in Serum, Hair, and Tumours from Patients with Esophageal cancer Nutr. Rep. Int., Volume 15, 1977
	Guidelines for Canadian Drinking Water Quality. Accessed August 2nd, 2017
	https://www.canada.ca/en/health-canada/services/environmental-workplace-health/reports-publications/water-quality/guidelines-canadian-drinking-water-quality-summary-table-health-canada-2012.html